



[7590-01-P]

## NUCLEAR REGULATORY COMMISSION

### 10 CFR Part 110

### NRC-2012-0008

#### Branch Technical Position on the Import of Non-U.S. Origin Radioactive Sources

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Request for comment.

**SUMMARY:** In 2010, the NRC published a final rule amending its regulations concerning export and import of nuclear equipment and material. Among other things, it added the phrase “Of U.S. origin” to the first exclusion to the definition of “radioactive waste”. The phrase was added to the final rule in response to a public comment on the proposed rule to clarify the exclusion. Since publication of the final rule, NRC staff has been engaged with industry in response to concerns raised regarding established industry practices and the need for guidance on implementation of the “U.S.-origin” exclusion.

**DATES:** Members of the public may submit written comments on the issues discussed in this notice. Comments on the issues presented in this notice should be postmarked no later than **[INSERT DATE: 60 DAYS FROM DATE OF PUBLICATION]**. Comments received after this date will be considered if it is practical to do so. NRC plans to consider these stakeholder views in the development of a final Branch Technical Position (BTP).

The proposed BTP is included in the SUPPLEMENTARY INFORMATION section of this document and is also available in NRC’s Agencywide Documents Access and Management System (ADAMS) under ML12278A170.

**ADDRESSES:** You may access information and comment submissions related to this document, which the NRC possesses and are publicly available, by searching on

<http://www.regulations.gov> under Docket ID NRC-2012-0008. You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- **Federal rulemaking Web site:** Go to <http://www.regulations.gov> and search for Docket ID NRC-2012-0008. Address questions about NRC dockets to Carol Gallagher; telephone: 301-492-3668; e-mail: [Carol.Gallagher@nrc.gov](mailto:Carol.Gallagher@nrc.gov).
- **Mail comments to:** Secretary, U. S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemaking and Adjudications Staff.
- **E-mail comments to:** [Rulemaking.Comments@nrc.gov](mailto:Rulemaking.Comments@nrc.gov). If you do not receive a reply e-mail confirming that we have received your comments, contact us directly at 301-415-1677.
- **Hand deliver comments to:** 11555 Rockville Pike, Rockville, Maryland 20852.
- **Fax comments to:** Secretary, U.S. Nuclear Regulatory Commission at 301-415-1101.

For additional direction on accessing information and submitting comments, see “Accessing Information and Submitting Comments” in the SUPPLEMENTARY INFORMATION section of this document.

**FOR FURTHER INFORMATION CONTACT:** Jennifer Tobin Wollenweber, Office of International Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-2328; e-mail: [Jennifer.Tobin@nrc.gov](mailto:Jennifer.Tobin@nrc.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. Accessing Information and Submitting Comments**

## A. Accessing Information

Please refer to Docket ID NRC-2012-0008 when contacting the NRC about the availability of information regarding this document. You may access information related to this document, which the NRC possesses and are publicly available, by any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov> and search for Docket ID NRC-2012-0008.

- **NRC's Agencywide Documents Access and Management System (ADAMS):** You may access publicly available documents online in the NRC Library at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "ADAMS Public Documents" and then select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to [pdr.resource@nrc.gov](mailto:pdr.resource@nrc.gov). The ADAMS accession number for each document referenced in this document (if that document is available in ADAMS) is provided the first time that a document is referenced.

- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

## B. Submitting Comments

Please include Docket ID NRC-2012-0008 in the subject line of your comment submission, in order to ensure that the NRC is able to make your comment submission available to the public in this docket.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at <http://www.regulations.gov> as well as enter the comment submissions into

ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submissions into ADAMS.

## **II. Background**

As a result of the *Federal Register* Notice (77 FR 2924) “Notice of Public Meeting and Request for Comment on the Branch Technical Position on the Import of Non-U.S. Origin Radioactive Sources,” published January 20, 2012, five comment letters were received for consideration by the NRC. At that time, the BTP was a working draft document with the intent of using feedback to enhance the document for publication of the revised proposed BTP for formal public comment. Of the comments made on the original draft BTP, most were comments on the existing rule rather than in the guidance that the BTP provides. The NRC response to these informal comments can be found at ML1255A106. Most of the comments did not oppose the underlying policy rationale and justification for the BTP’s proposal to construe “non-U.S. origin” disused sources as “U.S. origin” for the purpose of the first exclusion to the definition of “radioactive waste” under certain circumstances; instead, the comments appear to request NRC to revise or clarify the existing exclusions. Therefore, NRC did not consider these comments to be within the scope of the BTP. As a result of these comments, there are no substantive changes to the draft BTP. However, minor editorial changes were made to the draft BTP to provide greater clarity. This proposed BTP does not change the regulations in 10 CFR part 110;

it clarifies what is meant by “U.S. origin” and details how the NRC interprets this exclusion to the definition of “radioactive waste.”

### **III Branch Technical Position**

#### **A. Introduction**

The NRC’s regulations in 10 CFR part 110 (Part 110), “Export and Import of Nuclear Equipment and Material,” establishes the general and specific export and import licensing requirements for special nuclear, source, and byproduct material including radioactive waste. “Radioactive waste” is defined in 10 CFR 110.2 as “[a]ny material that contains or is contaminated with source, byproduct or special nuclear material that by its possession would require a specific radioactive material license in accordance with this Chapter [10 CFR Chapter I] and is imported or exported for the purposes of disposal in a land disposal facility as defined in 10 CFR Part 61, a disposal area as defined in Appendix A of 10 CFR Part 40, or an equivalent facility.”

There are six exclusions in 10 CFR 110.2 to the definition of “radioactive waste.” The sealed source exclusion (exclusion one) is defined as radioactive material that is “[o]f U.S. origin and contained in a sealed source, or device containing a sealed source, that is being returned to a manufacturer, distributor or other entity which is authorized to receive and possess the sealed source or the device containing a sealed source.”<sup>1</sup> Disused sources that satisfy an exclusion to the definition of “radioactive waste” may be imported under the general license in 10 CFR 110.27, which requires that the U.S. consignee be authorized to receive and possess the

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<sup>1</sup> The NRC provided the following guidance on the scope of “U.S. origin” on NRC’s Export and Import Web page at (<http://www.nrc.gov/about-nrc/ip/export-import.html>):

“U.S. origin was added in the first exclusion to the definition of radioactive waste to clarify that the exclusion only applies to sources of U.S. origin. U.S. origin sources may include sources with U.S. origin material and sources or devices manufactured, assembled or distributed by a U.S. company from a licensed domestic facility. Disused sources that originated in a country other than the United States would require a specific license if being exported or imported for disposal.”

material under the relevant NRC or Agreement State regulations and that the importer satisfy the terms for the general license set forth in 10 CFR 110.50.

The NRC has developed this technical position to provide guidance to source manufacturers, distributors, or other entity on the NRC's application of the sealed source exclusion to imports into the U.S. of non-U.S. origin disused sources.<sup>2</sup>

## B. Background

On July 28, 2010, the NRC published a final rule in the *Federal Register* (75 FR 44072) that amended several provisions in 10 CFR part 110 to improve NRC's regulatory framework for the export and import of nuclear equipment, material, and radioactive waste. The sealed source exclusion to the definition of "radioactive waste" was revised, in response to a comment, to confirm that the exclusion only applies to sources of "U.S. origin" being returned to an authorized domestic licensee. The addition of the term "U.S. origin" to the sealed source exclusion was consistent with the original intent of the exclusion, initially adopted in a 1995 rule.<sup>3</sup> In accordance with International Atomic Energy Agency (IAEA) Code of Conduct on the Safety and Security of Radioactive Sources and the IAEA supplemental Guidance on the Import and Export of Radioactive Sources, the NRC believed that encouraging return of disused sources to the country of origin would help prevent sources from becoming "orphaned" by facilitating responsible handling of sources at the end of their life cycle. See *Import and Export of Radioactive Waste*, 57 FR 17859, 17861 (July 21, 1992) (proposed rule) ("the return of used or depleted sealed sources, gauges, and similar items to the U.S. or to another original exporting country for reconditioning, recycling or disposal may...help ensure that such materials are handled responsibly and not left in dispersed and perhaps unregulated locations around the world"). The NRC's willingness to embrace this policy was in large part informed by U.S. industry comments that there is a "widely accepted practice, usually rooted in a sales or leasing

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<sup>2</sup> The terms "supplier" and "importer" are used interchangeably in this document with "manufacturers, distributors, or other entity."

<sup>3</sup> *Import and Export of Radioactive Waste*, 60 FR 37556 (July 21, 1995).

contract or other agreement, of returning depleted sealed radioactive sources, used gauges, and other instruments containing radioactive materials...to the original supplier-manufacturer for recycle or disposal." 57 FR 17864. See *also*, e.g., *id.* at 17861 ("the sale of a source is often conditioned on later return of the source for disposal"). Accordingly, central to the sealed source exclusion was the NRC's understanding, based on U.S. industry representations, that new and disused sources are routinely exchanged on a "one-for-one" basis – *i.e.*, a new source is exchanged for a disused source<sup>4</sup> – with the result that the number of disused sources imported is not greater than the number of new sources exported.

After the addition of "U.S. origin" to the sealed source exclusion in the 2010 rule, it came to the staff's attention that, while it remains a widespread industry practice to exchange new and disused sources on a "one-for-one" basis, in light of the current global supply market it is not always possible for a supplier to definitively ascertain the origin of a particular disused source that is exchanged for a new one before import and receipt of the disused source. With established customers, the disused sources will generally be of U.S. origin; however, for new customers, some of the sources initially being returned may not be of U.S. origin.

Once a source is imported and received, the manufacturer, distributor, or other entity technically has the ability to determine the source's origin. However, the only way for the supplier to accomplish this is by exposing its personnel to additional radiation doses. Specifically, the supplier must use a glove-box to take the source out of its casing to read the serial numbers and correlate those numbers to different manufacturer's coding patterns.

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<sup>4</sup> The sealed sources are changed out when the decay of the source limits the usefulness of the material. At this point, a supplier typically will send a new source and the user will return the used source in the same shielded container. This practice is typically formalized in the contract between the user and the supplier. Sometimes the sources are still useful and can be recycled for re-use in a different application. In that case, the sixth exclusion to the definition of "radioactive waste" applies and the source can be imported under a general license even if it is non-U.S. origin. Guidance on this exclusion can be found on NRC's Export and Import Web page at <http://www.nrc.gov/about-nrc/ip/export-import.html> and is in harmony with this position paper.

C. Regulatory Position

The NRC has construed the “U.S. origin” provision in the context of the industry’s recent clarification of international source exchange practices. The NRC recognizes that in some circumstances it may not be feasible for the importer to determine the country of origin for disused sources it seeks to exchange prior to import. If, after a good faith effort, the U.S. manufacturer, distributor, or other entity cannot determine whether an imported disused source that has been exchanged for a new source is of U.S. origin without exposing personnel to additional doses, the source in question shall be deemed to be of U.S. origin for the purposes of the sealed source exclusion to the definition of “radioactive waste” in 10 CFR 110.2.<sup>5</sup> This application of the sealed source exclusion is limited to disused sources imported into the United States that have been exchanged for a new source in a foreign country on a “one-for-one” basis. Accordingly, it is the NRC’s expectation that the number of disused sources imported by the manufacturer or distributor into the United States must not be greater than the number of new or refurbished sources exported by that manufacturer or distributor.

The NRC believes that this application of the sealed source exclusion reasonably balances the interests of public health and safety and international policy interests in responsible handling of sources at the end of their useful life. The approach preserves the fundamental policy rationale underlying the original exclusion – to prevent sources from being dispersed in unregulated locations around the world by facilitating a “one-for one” exchange of U.S.-supplied new and disused sources – while achieving occupational doses to workers that are as low as reasonably achievable, as specified in 10 CFR 20.1101(b).

The NRC expects U.S. manufacturers, distributors, and suppliers to inform their customers about U.S. import licensing requirements for disused sources. It is recommended that U.S. importers retain copies of their communications with their foreign customers regarding

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<sup>5</sup> The definition of “radioactive waste” in this Branch Technical Position paper pertains solely to export and import. It does not affect or alter the domestic regulations of “waste” as defined in 10 CFR 20.1003.



U.S. import requirements. The U.S. importer at all times must comply with the specific license requirement for disused sources known to be of non-U.S. origin prior to import into the United States. A good faith effort by the importer may include communication of U.S. import requirements with its foreign customers, examination of a photograph of the source the customer seeks to exchange, and other relevant information related to the disused sources' origin.

Consistent with 10 CFR 110.53, the NRC may inspect the licensee's records, premises and activities pertaining to its exports and imports to ensure compliance with the sealed source exclusion to the definition of "radioactive waste" by trying to determine source origin (from user paperwork and communication) before an import occurs.

This position is being distributed to all Agreement States and material licensees.

Additionally, the NRC has coordinated this position with the Department of Energy/National Nuclear Security Administration's (DOE/NNSA) Global Threat Reduction Initiative (GTRI). One of GTRI's programs repatriates sources from around the world that are in unsafe or insecure locations. The NRC does not have import licensing jurisdiction when U.S. companies import disused sources on behalf of NNSA's GTRI program; therefore, the licensing requirements in Part 110 would not apply to such imports.

#### D. Implementation

This technical position reflects the current NRC staff position on acceptable use of the general license for import of disused radioactive sources. Therefore, except in those cases in which the source manufacturer or distributor proposes an acceptable alternative method for complying with the definition of "radioactive waste" in Section 110.2, the guidance described herein will be used in the evaluation of the use of the general import license for disused sources.

Dated at Rockville, Maryland, this 15<sup>th</sup> day of October, 2012.

FOR THE NUCLEAR REGULATORY COMMISSION.

**/RA/**

Margaret M. Doane, Director,  
Office of International Programs.

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